

K112652

510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Mary Kruitwagen
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This summary was prepared on September 7, 2011

2. The name of the subject devices are the Philips SureSigns VS2⁺ Vital Signs Monitor and the Philips SureSigns VSi Vital Signs Monitor.

The trade names of the devices are the SureSigns VS2⁺ Vital Signs Monitor and SureSigns VSi Vital Signs Monitor.

The common usual name for both devices is multi-parameter patient monitor

3. The Classification names are as follows for the SureSigns VS2⁺:

Device Panel	Classification	ProCode	Description
Cardiovascular	870.1110, II	DSJ	Alarm, Blood Pressure
	870.1110, II	DSK	Computer, Blood Pressure
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive
	870.1435, II	DXG	Computer, Diagnostic, Pre-programmed, Single function
	870.2700, II	DQA	Oximeter
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical

The Classification names are as follows for the SureSigns VSi:

Device Panel	Classification	ProCode	Description
Cardiovascular	870.1110, II	DSK	Computer, Blood Pressure
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive
	870.2700, II	DQA	Oximeter
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical

4. The modified devices are substantially equivalent to previously cleared Philips devices, SureSigns VS2⁺ Vital Signs Monitor marketed pursuant to 510(k) K111114 cleared for software revision B.00 and for the VSi Vital Signs Monitor pursuant to 510(k) K110803 cleared for revision B.00. With this modification the software revision will be revision B.01. This is the first version of software that will be marketing on the SureSigns VS2⁺ and the SureSigns VSi vital signs monitors. The radio module is substantially equivalent to the wireless bridge used with the predicate SureSigns VS3 marketed pursuant to 510(k) K082280.
5. This submission is to announce the following modifications to the predicate VS2⁺ and VSi :
 - Addition of an internal radio module
 - Addition of several new accessories- SpO2 sensor and tabletop mount
 - EMC Emissions Class changed to Class A
6. The SureSigns VS2⁺ subject device has the same intended use and indications for use as the legally marketed predicate SureSigns VS2⁺ device. The SureSigns VS2⁺ Vital Signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Standard and optional parameters include: NBP, SpO2, and Temperature. Intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Additionally, the monitors may be used in transport situations within a healthcare facility.

The SureSigns VSi subject device has the same intended use and indications for use as the legally marketed predicate SureSigns VSi device. The SureSigns VSi Vital Signs monitor is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Standard and optional parameters include: NBP, SpO2, and Temperature. The SureSigns VSi vital signs monitor is intended for measurement of multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Additionally, the monitor is intended for use in transport situations within a healthcare facility.
7. The subject devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same design and algorithms as the predicate devices.
8. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject devices with respect to the predicates. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices, the specifications of the subject devices and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VS2⁺ Vital Signs and the Philips SureSigns VSi Vital Signs monitors meet all reliability requirements and performance claims and supports a determination of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Philips Medical Systems.
c/o Ms. Mary Kruitwagen
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810

Re: K112652
Trade/Device Name: Philips SureSigns Vs2+ Vital Signs Monitor, and Philips SureSigns
VS1 Vital Signs Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Codes: DXN, DQA, DSJ, DSK, DXG, DSA, FLL
Dated: September 9, 2011
Received: September 12, 2011

Dear Ms. Kruitwagen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

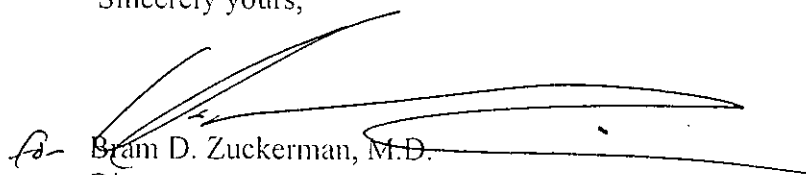
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): K112652

Device Name: SureSigns VS2⁺ (reference numbers: 863278, 863279)

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Standard and optional parameters include:

- NBP
- SpO2
- Temperature

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21.CFFR 801 Subpart D) (21 CFR 807 Subpart C)

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(Division Sign-Off)
Division of Cardiovascular Devices

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510(k) Number K112652

Indications for Use

510 (k) Number (if known): K112652

Device Name: SureSigns VSi (reference numbers: 863275, 863276, 863267)

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Standard and optional parameters include:

- NBP
- SpO2
- Temperature

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

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